



2006957

SAMPLING AND ANALYSIS PLAN
for the
VASQUEZ BOULEVARD AND I-70 NPL SITE

PHASE III BIOMONITORING
OF LEAD AND ARSENIC EXPOSURE

February 14, 2000

Prepared For:
U.S. Environmental Protection Agency, Region 8
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Contract No.: N00174-99-D-003
Delivery Order No.: 0002
Accounting No.: 99T8ALOP50102D 089RED00

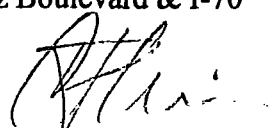
Purchase Request No.: 9203.3858
EPA IAG No.: DW17953800-01-0

APPROVAL PAGE

This Project Plan for the Vasquez Boulevard & I-70 Site – Biomonitoring Sampling and Analysis Plan has been prepared at the request of the U.S. Environmental Protection Agency, Region 8, by ISSI Consulting Group, Inc. Study investigations and activities addressed in this Project Plan are approved without condition.

Program Approval
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2/14/00
Date



Technical Approval
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TABLE OF CONTENTS

1.0	BACKGROUND AND STUDY OBJECTIVES	1
2.0	DATA QUALITY OBJECTIVES	2
3.0	FIELD SAMPLING PLAN	6
3.1	<u>Identification of Potentially Impacted Residences</u>	6
3.2	<u>Recruitment and Informed Consent for Biological Sampling</u>	7
3.3	<u>Collection of Biological Samples</u>	8
3.3.1	Participant Interviews	8
3.3.2	Sample Collection Methods	8
3.3.3	Sample Handling and Custody Requirements	8
3.3.4	Decontamination Procedures	9
3.4	<u>Field Documentation</u>	9
3.5	<u>Sample Identification</u>	10
3.6	<u>Sample Preparation</u>	10
3.7	<u>Analytical Method Requirements</u>	10
4.0	QUALITY ASSURANCE PROJECT PLAN	11
4.1	<u>Field Quality Control Samples</u>	11
4.2	<u>Detection and Quantitation Limits</u>	13
5.0	REFERENCES	14

FIGURES

- Figure 1 Example Requisition Form
Figure 2 Instructions for Completing Requisition Form
Figure 3 Data Collection Log

ATTACHMENTS

Attachment 1

1. Blood Lead Sampling (SOP # VBI70-13)
2. Composite Hair Sampling for the Determination of Risk-Based Exposure to Total Arsenic (SOP # VBI70-14)
3. Urine Sampling for the Determination of Risk-Based Exposure to Arsenic (SOP # VBI70-15)
4. Preparation and Analysis Methods for Lead in Blood, Total Arsenic in Hair, and Inorganic Arsenic in Urine

Attachment 2

1. Informed consent forms
2. Directions and instructions for providing samples
3. Example Requisition Form
4. Household Questionnaire
5. Child Questionnaire

TABLE OF ABBREVIATIONS

ACGIH	American Conference of Governmental Industrial Hygienists
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
COC	Chain of Custody
DQOs	Data Quality Objectives
MDL	Method Detection Limit
ppm	Parts Per Million
PQLs	Practical Quantitation Limits
QA/QC	Quality Assurance/Quality Control
SOPs	Standard Operating Procedures
UCL	Upper Confidence Limit
USEPA	United States Environmental Protection Agency
VBI70	Vasquez Boulevard and Interstate 70

1.0 BACKGROUND AND STUDY OBJECTIVES

The Vasquez Boulevard and I-70 (VBI70) site is an area located in north-central Denver, Colorado. On July 22, 1999, USEPA added this area to the National Priority List (NPL) of Superfund sites, making it eligible to receive federal funds for investigation and cleanup.

The site is characterized mainly by residential neighborhoods, with scattered commercial/ industrial properties. Investigations related to a nearby site (the Globe smelter) resulted in the observation that some residential properties in the VBI70 area have elevated levels of arsenic and/or lead in yard soils. EPA's initial studies at the site (referred to as Phase I and Phase II) revealed that contaminant levels (mainly arsenic) could be quite high in some properties, but that the spatial pattern was unpredictable (impacted properties often occur adjacent to unimpacted properties). A large-scale sampling plan referred to as Phase III Field Investigation is currently underway to obtain additional information on the pattern and extent of contamination (USEPA 1999a).

When elevated levels of arsenic and/or lead exist in soil, residents may be exposed by direct ingestion of the soil while working outdoors, or may be exposed indirectly by ingestion of indoor dust contaminated with soil. The hazards of such exposures can be estimated by using simple exposure and risk based models, but direct measurement of the actual level of exposure also provides useful information. Exposure to lead is generally evaluated by measurement of lead levels in blood. Exposure to arsenic may be evaluated either by measurement of arsenic in urine (this generally reflects recent exposures) or in hair (this generally reflects longer term exposures). Based on this, EPA established a program in conjunction with the Phase I and II studies to collect blood, hair and urine samples from individuals who resided at locations identified by EPA as being candidates for time-critical soil removal actions (USEPA 1998a,b; 1999b). Although limited, these biomonitoring data did not reveal any individuals with exposure levels that were clearly elevated or in a range of short-term health concern. Nevertheless, as Phase III sampling progresses, USEPA wishes to continue this voluntary biomonitoring program in order to promptly identify any individuals with exposures to lead and/or arsenic that are sufficiently high that short-term interventions may be needed to protect public health. Consequently, the objective of this component of the Phase III Field Investigation is to:

Collect biological samples from residents at properties known to contain elevated levels of lead and/or arsenic in order to identify individuals with exposures that are of potential short-term health concern.

2.0 DATA QUALITY OBJECTIVES

Data Quality Objectives (DQOs) are statements that define the type, quality, quantity, purpose and use of data to be collected. The design of a study is closely tied to the data quality objectives, which serve as the basis for important decisions regarding key design features such as the number and location of samples to be collected, the chemical analyses to be performed, etc.

USEPA has published a number of guidance documents on the DQO process (USEPA 1994, 1996, 1998c), and this sampling plan has been developed in accord with that guidance. In brief, the DQO process follows a seven-step procedure, as follows:

1. State the problem that the study is designed to address
2. Identify the decisions to be made with the data obtained
3. Identify the types of data inputs needed to make the decision
4. Define the bounds (in space and time) of the study
5. Define the decision rule which will be used to make decisions
6. Define the acceptable limits on decision errors
7. Optimize the design for obtaining data in an iterative fashion using information and DQOs identified in Steps 1-6

Following these seven steps helps ensure that the project plan is carefully thought out and that the data collected will provide sufficient information to support the key decisions which must be made. The following sections summarize the application of the DQO process to the design of the biomonitoring program.

Step 1. State the Problem

As the Phase III Field Investigation Project Plan is implemented, it is expected that some properties with elevated levels of lead and/or arsenic will be discovered. Limited biomonitoring data collected in association with the Phase I and Phase II investigations suggest that human exposures at properties with high levels of lead and/or arsenic may not be as high as predicted by traditional USEPA exposure models. However, these biomonitoring data are not sufficient to conclude that cases of immediate health concern might not occur at properties discovered during Phase III. Therefore, in order to be protective, USEPA seeks to obtain direct estimates of exposure to lead and arsenic in individuals who live at locations with high arsenic or lead levels in soil in order to judge what actions, if any, need be taken immediately.

Step 2. Identify the Decision to Be Made

The decision to be made is whether a short-term intervention is needed at a residence where elevated levels of lead and/or arsenic have been discovered. Note that a short-term intervention

might take a number of forms, ranging from simple education of residents regarding protective steps they might take to an actual removal of contaminated soils. Also note that a finding that no short-term intervention is needed at a property is not equivalent to a decision that no remedial (non-time-critical) action is needed. Indeed, it is expected that properties with soil levels high enough to warrant biomonitoring are likely candidates for remedial action. However, EPA will not make final remedial decisions until after collection of all site specific data and completion of the risk assessment.

Step 3. Identify Types of Input Needed

Two types of input are needed to reach this decision: 1) the location of properties with lead and/or arsenic levels in a range that might be of short-term health concern, and 2) the blood lead levels and the hair or urine arsenic levels of individuals residing at those locations. The location of properties with elevated levels of lead and/or arsenic in soil will be identified using the results of the Phase III residential yard soil investigation. Measurements of lead and arsenic in biological tissues will be obtained from this biomonitoring project.

Step 4. Define the Bounds of the Study

All residential properties located within the current boundaries of the VBI70 study area that have elevated levels of lead and/or arsenic in yard soil are candidates for biomonitoring. Soil levels which indicate the need for biomonitoring are summarized below.

Arsenic Levels that Warrant Biomonitoring

Calculations performed by USEPA (1998a) suggest that arsenic levels in the range of 400 - 900 ppm in yard soil might pose a short-term health risk to residents. Based on this information, biomonitoring during Phase III will focus on properties where arsenic levels exceed 400 ppm.

Lead Levels that Warrant Biomonitoring

As discussed in the same document (USEPA 1998a), lead levels above 2,000 ppm in yard soil might be of short-term health concern to residents. On this basis, a level of 2,000 ppm in soil is identified as the level where biomonitoring of blood lead should occur during Phase III to identify any cases of short-term concern.

Step 5. Define the Decision Rule

Arsenic

Arsenic is a normal component of the environment and is present at low levels in water, food and soil. Because of this, arsenic is expected to be present in low levels in the urine and the hair of all individuals. Data are not extensive on the normal range of arsenic in hair and urine of individuals with no special exposures, but data provided in ACGIH (1991) and from National Medical Services (Attachment 1) suggest the following values are likely to be representative of unexposed individuals:

Tissue	Normal Range
Hair	< 1 ug/g
Urine (total)	< 50 ug/L or < 50 ug/g creatinine
Urine (inorganic)	< 20 ug/L

Any individual with a hair measurement and urine measurements that fall within the normal range will not be considered as a candidate for any short-term intervention. Any individual with hair and/or arsenic levels that exceed the upper end of the normal range will be considered as a candidate for some sort of short-term intervention, with the nature of the intervention depending on the measured levels of arsenic in soil and or dust in the house and on the magnitude of the elevation in the biomonitoring parameter. Repeat testing of hair and/or urine will always be sought before any short-term actions or interventions are implemented.

Lead

The Centers for Disease Control and Prevention (CDC) has established recommended guidelines for the appropriate response to elevated blood lead levels detected in an individual (the levels are designed specifically for children, but may conservatively be used to evaluate adults as well). These guidelines are summarized below:

Blood Lead (ug/dL)	Recommended Response
< 10	No action; levels are not of concern
10-14	Provide information about ways to reduce lead exposure. <u>Re-test in one year.</u>
15-19	Provide information about ways to reduce lead exposure. <u>Re-test in one month.</u>
20-44	Perform a full medical evaluation and environmental management assessment.
> 45	Urgent medical follow-up and environmental management assessment is required.

a - Developed from the CDC guidelines (October 1991).

In accord with these guidelines, only locations where one or more individuals has a blood lead level exceeding 20 ug/dL will be considered as a candidate for a short-term intervention. Note that short-term harm is not expected at a blood lead level of 20 ug/dL, but this value is sufficiently high that prompt action to identify sources and reduce exposures is warranted. At locations where blood lead levels are less than 20 ug/dL but higher than 10 ug/dL, USEPA will provide the residents with information on ways in which lead exposure may be reduced until a final remedial decision is made.

Step 6. Identify Acceptable Limits on Decision Errors

Two types of potential decision error are associated with this project:

- 1: Intervening in a case where the risk of short term harm is actually minimal.
- 2: Failing to intervene in a case where the risks of short term harm are significant.

There is little or no disadvantage to making an error of the first type, except that this action might cause undue alarm or concern in the residents. However, with proper counseling and follow-up monitoring, this is not considered to be a serious problem. In contrast, an error of the second type is highly undesirable and low error rate must be sought. In this regard, there are two places where an error might occur:

- 1) *Incorrectly classifying a property as being below the level where biomonitoring is needed, when the true level is actually above this level.* When evaluating the need to recruit residents at a property to participate in the biomonitoring program, the estimate of the concentration of arsenic in the yard will be based on the 95% UCL of the arithmetic mean concentration. In the case of lead, the decision will be based on the arithmetic

mean. This is because the level of health concern for lead is calculated in such a way that at least 95% of all children exposed to that level will be protected. These two approaches ensure that essentially all properties where either arsenic and/or lead are above the level of potential short-term health concern will be identified for recruitment into the biomonitoring program.

- 2) *Not intervening in the case of an individual whose exposure levels are of short-term health concern.* With regard to the decision to implement short-term intervention or not, it is believed that each of the biomonitoring criteria established above are conservative (i.e., a small exceedence of the criterion is associated with only minimal risk of short-term health effect), so the probability of not intervening in a case in which there is an authentic and significant risk of short term harm is considered to be minimal. As an added precaution, any individuals who have biomonitoring results that approach but do not exceed the levels that are considered to be of short-term health concern will be strongly encouraged to provide one or more additional samples in order to characterize the true level of exposure more precisely.

Step 7. Optimize the Design

The basic design of this project may be refined as information becomes available on the number of properties that may warrant biomonitoring and on the arsenic and lead exposure levels observed in residents at those locations. Criteria for inclusion of a property in the biomonitoring study may be either increased or decreased as these data are received.

3.0 FIELD SAMPLING PLAN

Based on the data quality objectives outlined above, the key components of the field sampling plan needed to collect the necessary biomonitoring data are summarized below.

- Step 1: Identify properties that have arsenic and or lead levels high enough to warrant biomonitoring.
- Step 2: Contact residents at the selected properties and recruit their voluntary participation in the biomonitoring program.
- Step 3: Collect biological samples (hair, urine and blood) from all volunteers who participate in the program.
- Step 4: Measure arsenic levels in hair and urine and lead levels in blood, using methods that are sufficiently sensitive and accurate to detect exceedences that are in a range of short-term health concern.

Step 5: Take appropriate action to intervene in any case where exposure levels exceed a criterion for risk of short term harm.

Specific tasks needed to perform each of these basic steps and achieve the objectives of the study are presented below.

3.1 Identification of Potentially Impacted Residences

As stated previously, residences will be selected for biomonitoring based on the results from the surficial yard soil portion of the Phase III field investigation. The criteria used to identify residences where biomonitoring will be recruited are as follows:

Chemical	Criteria for Yard Soil Levels
Arsenic	95% UCL of mean > 400 ppm
Lead	Mean > 2000 ppm

ISSI will notify USEPA within one week whenever a property is identified that exceeds one or both of these criteria.

3.2 Recruitment and Informed Consent for Biological Sampling

As noted earlier, this biomonitoring program is strictly voluntary. Residents living in properties where lead and/or arsenic levels are of potential short-term health concern will be contacted by USEPA staff in a personal visit. Each will be informed of the reasons they are being contacted and provided a fact sheet that summarizes the basis for potential concern and explains the benefits of participating in the biomonitoring program.

All individuals who give consent to participate in the biomonitoring program will be given a package (see Attachment 2) which contains the following:

- An informed consent form for each individual. This form must be signed and provided to the clinic before any samples will be collected. For children under age 18, permission must be granted by their parent or guardian prior to sampling.
- A letter summarizing the reason that biomonitoring is believed to be desirable, instructions for where and how to provide the biological samples. This includes a map showing the location of the clinic, along with the phone number and a schedule of regular clinic hours. In addition, a fact sheet will be provided that shows how to reduce the risk of exposure to arsenic and lead.

- A Data Collection Log that will be used by the clinic to track the number of participants and the number of samples collected during their visit.
- A requisition form that will be used by the laboratory to document each sample collected.
- Questionnaires to be completed by each participant

3.3 Collection of Biological Samples

3.3.1 Participant Interviews

Prior to sample collection, an interview/survey will be conducted for each participating resident. Information provided during these interview/surveys will help provide information that may be useful in subsequent risk calculations. This survey form is included in Attachment 2.

3.3.2 Sample Collection Methods

All biological samples will be collected in accord with the Standard Operating Procedures (SOPs) specific to each type of media:

- Blood collection (SOP # ISSI-VBI70-13)
- Hair collection (SOP # ISSI-VBI70-14)
- Urine collection (SOP # ISSI-VBI70-15)

Each of these SOPs is provided in Attachment 1.

At least one sample of the appropriate biological media will be collected from each participant. Duplicate samples will be collected from willing participants in accord with the frequency specified in Section 4.0.

3.3.3 Sample Handling and Custody Requirements

Samples must be kept under strict chain-of-custody at all times. Samples will be locked and stored under chain-of-custody at the clinic until they are forwarded to the analytical laboratory for sample preparation and analysis. A sample is in an individual's custody if:

- It is in his/her possession
- It is in his/her view, after being in their possession

- It was in his/her possession and he/she either locked it or placed it in a sealed container to prevent tampering
- It is in a designated secure area

Chain-of-custody (COC) forms will be prepared for every sample collected immediately following collection of each sample. The Analysis Requisition form will serve as the COC form for all samples. An example requisition form is provided in Figure 1. Instructions for completing the form are provided in Figure 2.

Any samples in glass containers will be packaged for shipment using bubble wrap or equivalent packing materials. Containers carrying blood samples must be chilled using the blue ice packets provided by the analytical laboratory. Hair and urine samples will be transported using coolers, but temperature preservation is not required.

All samples shipped to the laboratory will be contained in a plastic cooler with packing material, if necessary, to prevent excessive agitation of the contents. All coolers will be securely taped closed, sealed with a minimum of two signed custody seals and labeled with a completed air bill prior to shipment.

3.3.4 Decontamination Procedures

Biological sampling equipment will not be re-used with one exception. Therefore, typically decontamination is not required. However the scissors used for clipping hair samples will be cleaned between samples using alcohol wipes. All personnel collecting biological samples will wear a new pair of disposable gloves for each sample collected. Proper disposal of all sampling equipment and materials is described in the appropriate SOPs (Attachment 1).

3.4 Field Documentation

When an individual visits the clinic to provide a sample of hair, urine, and/or blood, a requisition form and Data Collection Log must be completed to document the sample. Examples of the requisition form, Figure 1. Information contained in the requisition and the COC form includes the following:

1. Sample collection date and time
2. Name of the individual
3. Type(s) of sample (urine, blood or hair)
4. Chemical analyses requested on each sample (lead and/or arsenic)
5. Sample numbers assigned to each sample

An example of the Data Collection Log is provided in Figure 3. Information contained in the

Data Collection Log includes the following:

1. Sample number
2. Date collected
3. Time of collection for each medium (urine, blood or hair)
4. Technician's initials for each medium (urine, blood or hair)
5. Comments or notes of importance (if sample is a duplicate, or any deviations to SOP)

Copies of the requisition forms, COC forms, and the Data Collection Logs will be sent to USEPA's contractor (ISSI Consulting Group, Inc. [ISSI]) after each day of sampling. These copies will be stored in a three-ring binder book maintained by ISSI.

3.5 Sample Identification

Every biological and QC sample collected during this investigation will be identified with a unique sample identification number. Sample identification labels are found on the Analysis Requisition form. One label will be affixed to each biological sample container, so that the same sample ID is used for all samples collected from a participant. Duplicate samples will be identified by using an imaginary patient name to maintain anonymity at the analytical laboratory. The actual patient name must be identified in the Comments field of the Data Collection Log.

3.6 Sample Preparation

Blood

Blood samples will be prepared prior to analysis according to the procedure described in National Medical Services Method Number 6020 (Attachment 2).

Urine

Urine samples will be prepared prior to analysis according to the procedure described in National medical Services Method Number 0468 (Attachment 2).

Hair

Hair samples will be prepared prior to analysis according to the following procedure.

Wash hands thoroughly with soap and water prior to handling hair sample. Put on a new pair of disposable latex gloves for each sample. Open sealed bag and remove vial cap. Remove half of the sample (about 0.2 g) and place in a new 15 x 100 mm disposable plastic petri dish. Wash

with successive portions of 1.0% w/v sodium lauryl sulfate (or ammonium lauryl sulfate). After 30 minute contact with occasional agitation, the hair will be rinsed six times with deionized water and dried under laminar flow Class 100 air.

3.7 Analytical Method Requirements

The analytical method and project-required detection limits (PQLs) for each type of biological media being collected are provided in the tables below. Analytical method numbers refer to the numbering system used by National Medical Services, the analytical laboratory that will be used for this study.

Analytical Methods

Analyte	Biological Sample Media					
	Hair	Method No.	Urine	Method No.	Blood	Method No.
Arsenic (inorganic)	--	--	FIAS ^b	0468	--	--
Arsenic (total)	GFASS ^a	0460	--	--	--	--
Lead (total)	--	--	--	--	GFASS ^a	6020

^a - Graphite Furnace Atomic Absorption Spectroscopy

^b - Flow Injection Atomic Spectroscopy

Project-Required Detection Limits

Analyte	Biological Sample Type		
	Hair	Urine	Blood
Arsenic (inorganic)	--	10 ug/L	--
Arsenic (total)	1 ug/g	10 ug/L or 10 ug As/g creatinine	--
Lead	--	--	1 ug/dL

These methods are sufficiently accurate and sufficiently sensitive that any individual with exposure to lead or arsenic that is in a range of potential short-term health concern will be identified with high confidence.

4.0 QUALITY ASSURANCE PROJECT PLAN

The complete Quality Assurance Project Plan (QAPP) for the VBI70 Phase III Field

Investigation has been prepared in accordance with USEPA guidance documents. Quality assurance steps pertaining specifically to the biomonitoring program of Phase III are provided below.

4.1 Field Quality Control Samples

A number of quality control samples will be collected during this project to help assess the precision and accuracy of the data collected. These samples are described below.

Field Duplicate: Field duplicate samples are collected at the same time as the primary sample, and are submitted blind to the analytical laboratory to test both the precision of the analysis and the precision of sample collection. A minimum of 3 field duplicates will be collected from participating adults. If the number of participants exceeds 50, field duplicate samples will be collected at a frequency of 5% of all samples collected (1 field duplicate per 20 investigation samples collected).

Field duplicates are defined as the following:

Blood:	A second vial of blood drawn from the same individual
Hair:	A second sample of hair collected from the same individual
Urine:	A second sample of urine provided by the same individual immediately after collection of the first sample

Acceptance criteria for field duplicates is described in Section 4.8.1 of the Phase III Field Investigation Project Plan.

Blind Standard: The accuracy of an analytical method is evaluated by analyzing a sample medium fortified with a known concentration of target analytes that has been certified using the preparation and analysis method for that particular sample medium. The requirements for insertion of blind standards into the sample stream for each medium are presented below.

Blood

Blind standards for blood will be obtained from the University of Cincinnati. Two concentration levels will be used during this study, approximately 3 ug/dL and 15 ug/dL. A minimum of 3 blind standards (at each level) will be submitted to the analytical laboratory in a blind fashion. If the total number of blood samples exceeds 50, additional blind blood standards will be submitted to the analytical laboratory at a rate of about 5% (1 blind standard per 20 investigative samples). Results will be considered acceptable if the results for blind standards fall within the acceptance criteria established by the certifying laboratory approximately 95% of the time.

Urine

A minimum of 3 blind standards (at each of two levels) will be submitted to the analytical laboratory in a blind fashion. If the total number of urine samples exceeds 50, additional blind urine standards will be submitted at a rate of about 5% (1 blind standard per 20 investigative samples). Results will be considered acceptable if the results for blind standards fall within the acceptance criteria established by the certifying laboratory approximately 95% of the time.

Hair

A source to obtain blind standards was not located. Therefore, analytical accuracy for hair analysis will be assessed by reviewing matrix spike analyses performed by the laboratory.

4.2 Detection and Quantitation Limits

The Method Detection Limit (MDL) is defined as the concentration of a substance that can be recognized as being greater than zero with 99% confidence. Typically, the MDL is defined as 3-times the standard deviation of seven replicate analyses of a site sample containing a low but detectable level of the analyte. The Practical Quantitation Limit (PQL) is generally defined as 10-times the standard deviation determined from the MDL study (or often described as 3 times the MDL). A MDL study must be performed for each method utilized in the study in accord with guidance outlined in the 40 CFR Part 136, Appendix B. Results that are below the PQL, but above the MDL will be qualified with a 'B' flag and reported as estimated results.

5.0 REFERENCES

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**VBI70 Biomonitoring
Sampling and Analysis Plan**

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USEPA. 1999a. Project Plan for the Vasquez Boulevard and I-70 Site Phase III Field Investigation. Prepared by ISSI Consulting Group, Inc. August 4, 1999.

USEPA. 1999b. Draft Report for the Vasquez Boulevard and I-70 Site Residential Risk-Based Sampling Stage I Investigation. Prepared by ISSI Consulting Group, Inc. April 1999.

FIGURES

Figure 1

ANALYSIS REQUISITION


National Medical Services, Inc.

 3701 Welsh Rd. • P.O. Box 430A
 Willow Grove, Pennsylvania 19090-0437
 (215) 857-4900 (800) 622-6871 FAX: (215) 657-2972

 Biomonitoring for Environmental/Occupational Exposure • Criminalistics
 Forensic Toxicology • Therapeutic Drug Monitoring

• CLIENT TO FILL IN SHADED AREAS ONLY •

PATIENT NAME (LAST, FIRST, M.I.) **DOE, JOHN**

PATIENT I.D. NO. **38 3 14**

☐ FORENSIC ☒ STAT ☐ Return Specimen

NOTE: REQUISITIONS WILL BE HANDLED AS NON-FORENSIC UNLESS OTHERWISE INDICATED. REFER TO SERVICES DIRECTORY FOR FORENSIC CASE HANDLING INSTRUCTIONS.

SPECIMEN TYPE:

☒ Blood ☒ Urine ☐ Other _____ SPECIFY _____

☐ Plasma ☐ Hair ☐ Tissue _____ SPECIFY _____

☐ Serum ☐ Tissue _____ SPECIFY _____

SPECIMEN COLLECTION:

Date: **10/16/98**

Time: **1345**

Urine: ☒ Random ☐ Timed Sample

Time: _____ HRS.

Volume: _____ MLE

 CONTROL NO. **000000**

 ACCOUNT NO. **00000**


ACCOUNT NAME/ADDRESS

COMPANY NAME ISSI
ADDRESS 9918th St
ADDRESS Suite 1450
CITY STATE ZIP Denver, CO 80202

 ACCOUNT INFORMATION
 (e.g. alias of patient, medication)

10

TEST CODE	TEST NAME	TEST CODE	TEST NAME
0264	ALUMINUM	1850	DRUG SCREEN & ALCOHOL (BLOOD OR URINE)
0407	ARSENIC (SPECIATED)	1884	DRUG SCREEN (BLOOD OR URINE)
0480	ARSENIC (TOTAL)	8489	FENTANYL + METAB. (FORENSIC)
0641	BENZENE (BLOOD)	2124	FLUVOXAMINE (LUVOX®)
8328	BENZODIAZEPINES W/GC/MS†	2134	FORMIC ACID
0820	BENZTROPINE (COGENTIN®)	2143	GABAPENTIN
0803	BUPROPION (WELLBUTRIN®)*	2321	HYDROCARBON + OXYGENATED VOLATILES
0805	BUSPIRONE (BUSPAR®)	2390	IBUPROFEN
0921	CADMIUM BIOUPTAKE (BLOOD)	2418	INHALANTS - URINE METABS.
8108	CADMIUM PANEL (OSHA)	2440	ISONIAZID*
0860	CANNABINOIDS (THC) W/ GC/MS	2484	LAMOTRIGINE (LAMICTAL®)
0870	CARBAMAZEPINE + METABOLITE	2402	LEAD - SERUM
0971	CARBAMAZEPINE + METAB. - FREE	8020	LEAD IN BLOOD
0872	CARBAMAZEPINE + METAB. - FREE/BLOOD	2541	LBD SCREEN†
1268	CHOLINESTERASE (RBC OR PLASMA)	2551	MAGNESIUM
1261	CHROMIUM	2570	MANGANESE
1268	CLOMIPRAMINE AND METAB.	2670	MERCURY
1275	CLONIDINE	6153	METALS PANEL - RBC's
1287	CLOZAPINE + METABOLITE	2681	METALS/METALLOIDS† (BLOOD)
1300	COCAINE + METAB. W/ GC/MS	3020	METHYLPHENIDATE (RITALIN®)*
1330	COPPER	3145	NEFAZADONE
3183	COTININE - URINE	3180	NICOTINE + COTININE METAB.
1840	DILTIAZEM	8880	OPIATES - FREE (ACTIVE) W/GC/MS
		4844	ZINC

 CONTROL NUMBER **000000**


NMS - WILLOW GROVE 18090-0437

 CONTROL NUMBER **000000**


NMS - WILLOW GROVE 18090-0437

 CONTROL NUMBER **000000**


NMS - WILLOW GROVE 18090-0437

 CONTROL NUMBER **000000**


NMS - WILLOW GROVE 18090-0437

 IF ANALYSIS DOES NOT APPEAR ABOVE,
 PLEASE WRITE TEST NAME/NUMBER IN SPACE PROVIDED BELOW.

Hair = test code 0460

 Blood = ¹² test code 6020

Urine = test code 0468

R Note _____ Tgmt _____

PL

RT	BYT	RBYT	BLT	BT	LT	CPC	GPC	GYPC	PPC	OPC
BLV	WV	VV	CV	RV	DV	LDLV	HB	WPO	BLPO	RPO
BRV	GV	LV								

VERIFICATION:

NMS COPY

VER 1.7

**FIGURE 2:
INSTRUCTIONS FOR COMPLETING
CLINICAL ANALYSIS REQUISITION FORM**

NMS Analysis Requisition are multi-copy perforated forms that include unique specimen identification Control Number labels (see Attachment 2 for example). When completing this form, please press firmly to ensure information is transferred to each page.

The Analysis Requisition Form, as shown in Figure 1, has been divided into numbered sections from 1 to 12, specifically for instructional purposes. Not all sections are required for this study. Fill each section out as follows:

1. Name - Print participant's name clearly, last name first
2. Social Security Number
3. Age
4. Sex
5. Forensic - Leave blank
6. Stat - Leave blank
7. Return Specimen - Leave blank
8. Specimen type - All requisition forms should have checkmarks in the boxes for blood, urine, and hair samples when samples have been collected
9. Specimen Collection - The following information is requested:
 - Date of specimen collection
 - Time (in military time) of specimen collectionFor urine samples:
 - Box marked "Random" should be checked, and "Timed Sample" left unchecked
 - Elapsed time - shouldn't be any
 - Volume - estimated urine sample volume, in ml
10. Additional information - Indicate any pertinent information or observations regarding the participant's history
11. Indicate the requested analytical method number in the space provided (as indicated in the example) by marking an "X" in the following boxes:
 - 0460 - Arsenic Hair (total)
 - 0468 - Arsenic Urine (inorganic)
 - 6020 - Lead in Blood

Remove the pressure sensitive Control Number labels from the top copy of the Analysis Requisition and securely apply one label to each specimen submitted per requisition.

Remove the last copy of the Analysis Requisition and place in the Field Notebook behind the Data Collection Log.

Data Collection Log

Date: _____

ATTACHMENT 1

SOPs for COLLECTION OF BIOLOGICAL SAMPLES

SOP Title

1. Blood Lead Sampling (SOP # VBI70-13)
2. Composite Hair Sampling for the Determination of Risk-Based Exposure to Total Arsenic (SOP # VBI70-14)
3. Urine Sampling for the Determination of Risk-Based Exposure to Arsenic (SOP # VBI70-15)
4. Preparation and Analysis Methods for Lead in Blood, Total Arsenic in Hair, and Inorganic Arsenic in Urine

VBI70 Biomonitoring
Sampling and Analysis Plan

Blood Lead Sampling
(SOP # VBI70-13)

Date: November 30, 1999 (Rev. # 0)

SOP No. ISSI-VBI70-13

Title: BLOOD LEAD SAMPLING

APPROVALS:

Author _____ ISSI Consulting Group, Inc. _____

Date: November 30, 1999

SYNOPSIS: A standardized method for the collection of blood samples for subsequent determination of risk-based exposure to lead. Protocols for sample collection, and sample handling are provided.

Received by QA Unit:

REVIEWS:

TEAM MEMBER

SIGNATURE/TITLE

DATE

EPA Region 8

[Signature] Rev 2/14/00

ISSI Consulting Group, Inc.

WS Brathen 2/15/00

Revision Date	Reason for Revision

TECHNICAL STANDARD OPERATING PROCEDURE

BLOOD LEAD SAMPLING

1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to provide a standardized method for collecting blood for subsequent determination of exposure to lead. Blood samples from subjects recruited into the study will be collected at a neighborhood clinic by study personnel. Trained phlebotomists will collect these samples using venipuncture collection techniques. All personnel involved with the blood collection will be trained in this procedure. This SOP describes the equipment and operations used for collecting blood, using a procedure that will produce data that can be used to support risk evaluations. Site-specific deviations from the procedures outlined in this document must be approved by the USEPA Region 8 Remedial Project Manager, or Regional Toxicologist prior to initiation of the sampling activity.

2.0 RESPONSIBILITIES

The contractor who is responsible for overseeing the biomonitoring activities (ISSI) will be responsible for checking all work performed and verifying that the work satisfies the specific tasks outlined by this SOP and the Project Plan. It is also the responsibility of the contractor to communicate the need for any deviations from this SOP with the appropriate USEPA Region 8 personnel (Remedial Project Manager, or Regional Toxicologist). It is the responsibility of the subcontractor collecting the sample (Concentra) to communicate with all personnel regarding specific collection objectives and to communicate with ISSI regarding any anticipated situations that require deviation from this SOP.

All personnel performing biological sampling are responsible for adhering to the applicable tasks outlined in this procedure while collecting samples.

3.0 EQUIPMENT

- Collection containers - certified lead-free Vacutainer tubes preserved with EDTA
- Vacutainer winged collection set (butterfly)
- Gloves - Disposable, latex, powderless.
- Tube holder
- Syringe
- Alcohol pads
- Gauze sponges (2 x 2s)
- Band-aids
- Tourniquet
- Analysis Requisition forms - will be provided by ISSI
- Consent form - will be provided by ISSI
- Field notebook - a three-ring binder book that will store necessary forms used to record and track samples collected as part of the VBI70 biomonitoring program.

TECHNICAL STANDARD OPERATING PROCEDURE

BLOOD LEAD SAMPLING

Binders will contain sample requisition forms and Data Collection Logsheets and Analysis Requisition forms.

4.0 METHOD SUMMARY

Every effort must be made to avoid lead contamination. The skin will be thoroughly cleansed prior to sample collection. Caps will never be removed from Vacutainer tubes prior to, or during sampling. Samples will be clearly marked with the patient's name, date of collection, and patient's social security number.

5.0 COLLECTION OF BLOOD SAMPLES

5.1 Venipuncture

A new pair of disposable gloves are to be worn for each new patient.

Venipuncture samples will be drawn using a 23 gauge butterfly apparatus attached to a tube holder or a syringe. Prior to collection, all necessary supplies and equipment should be laid out on a clean tray. Wash hands well with soap and water, and then put on a new pair of gloves. Locate the puncture site, and apply a new alcohol wipe to the site. Hold the puncture site by pinching either end of the alcohol wipe so that only the alcohol wipe is touching the patient's skin. Wipe the area in a circular motion beginning with a narrow radius and moving outward so as not to cross over the area that has already been cleaned. Repeat this action with a new alcohol wipe to remove any lead particles adhering to the skin.

Locate the vein and apply the tourniquet. Fix the vein by pressing down on the vein about 1 inch below the proposed point of entry, and pull the skin taut. Approach the vein from the same direction the vein is running, holding the sterilized needle at a 15-degree angle with the patient's arm. Push the needle, bevel side facing up, quickly and deliberately into the vein. If the needle is in the vein, blood will flow freely through the butterfly tubing and into the tube. If no blood enters the tube, probe for the vein carefully (avoid hematoma formation) until entry is indicated by blood flowing into the tube. Fill the Vacutainer tube with at least 1.5 - 2cc of blood. When sampling is complete, remove the tourniquet and then extract the needle from the vein. With the arm elevated, allow the patient to hold a clean gauze sponge onto the puncture wound, until the wound has clotted. Secure with a band-aid.

If the patient is less than 1 year old or is very small, a syringe attached to the butterfly tubing should be used instead of the Vacutainer tube. This will avoid collapsing the veins of very small children. Once the needle is in the vein and blood can be seen in the butterfly tubing, aspirate the syringe. Gently fill the syringe collecting approximately 2 ml of blood. Remove the tourniquet during this process and then extract the needle from the vein. Allow the patient or a parent to hold a clean gauze sponge onto the puncture wound. Fill the Vacutainer tube by puncturing the top and *gently* releasing blood into the tube.

TECHNICAL STANDARD OPERATING PROCEDURE

BLOOD LEAD SAMPLING

After collection, immediately invert the Vacutainer tube, and gently repeat this process several times to mix the sample with the EDTA preservative. Remove disposable gloves and dispose of these and all other blood collection equipment in an appropriate container designated for sharps or biological waste. Wash hands.

6.0 SAMPLE CONTAINERS AND LABELING

Following the procedures outlined in Section 5.0, samples will be collected directly into sample containers (Vacutainer tubes) and labeled with a unique sample identification number. Each sample must have an identification number affixed to the collection tube, and also attached to the Analysis Requisition form.

7.0 SITE CLEAN-UP

Dispose of needles in a container designated for sharps. Blood saturated materials must be disposed of in a container designated for biological waste.

8.0 FIELD QUALITY ASSURANCE/QUALITY CONTROL

Adherence to quality assurance/quality control (QA/QC) procedures is an important part of field sample collection. Field QA/QC procedures include documentation requirements and preparation of field QC samples.

8.1 Field Quality Control Samples

The following quality control samples will be collected during this project to help assess the precision and accuracy of the data collected.

Field Duplicate: Field duplicate samples are collected at the same time as the primary sample, and are submitted blind to the analytical laboratory to test both the precision of the analysis and the precision of sample collection. In this case, the field duplicate sample is a second sample of blood drawn from the same individual, by fitting a second tube onto the butterfly or syringe immediately after filling the first tube. A minimum of 3 field duplicates will be collected from participating adults. If the number of samples exceeds 50, field duplicate samples will be collected at a frequency of 5% of all samples collected (1 field duplicate per 20 investigation samples collected). Field duplicate samples are submitted in a blind fashion to the analytical laboratory. In order to maintain anonymity, field duplicates will be labeled with 'dummy' patient names and inserted into the sample stream. A list of 'dummy' patient names is provided in Attachment 2. Direction for the selection and submission of field duplicates will be the responsibility of ISSI.

Blind Standard: The accuracy of an analytical method is evaluated by analyzing a sample

TECHNICAL STANDARD OPERATING PROCEDURE

BLOOD LEAD SAMPLING

medium fortified with a known concentration of target analytes that has been certified using the preparation and analysis method for that particular sample medium. Blind standards will be inserted into the sample stream using 'dummy' patient names to maintain the anonymity of the sample. A minimum of 3 blind standards at 2 lead concentrations will be inserted into the sample stream by ISSI.

8.2 Field documentation

A field notebook should be maintained by the personnel collecting blood samples. The field notebook is a three-ring binder that contains a Data Collection Log and the Analysis Requisition form for each patient. All entries in the field logbook must be signed and dated by the person recording the information.

The following information will be included on the Data Collection Log;

- date of collection
- time of collection
- name of sampling technician
- patient name
- sample identification number
- descriptions of any deviations to this SOP and the reason for the deviation

An example of the Analysis Requisition form and the Data Collection Log is provided in Attachment 1.

9.0 DECONTAMINATION

Biological sampling equipment will not be re-used. All sampling equipment must be disposed in appropriate containers designated for biological waste.

10.0 GLOSSARY

Project Plan - The written document that spells out the detailed site-specific procedures to be followed by the Project Leader and the Clinic Personnel.

11.0 REFERENCES

Bornschein, 1989. 1989 Midvale Community Blood Lead Study Protocols.

MDPH (Massachusetts Department of Public Health). Procedure for obtaining finger stick blood samples. Jamaica Plain (MA): MDPH, Childhood Lead Poisoning Program, 1990.

MHD (Milwaukee Health Department). Generalized procedure finger stick blood (hematocrit and/or lead test). Milwaukee: MHD, 1988.

TECHNICAL STANDARD OPERATING PROCEDURE
BLOOD LEAD SAMPLING

ATTACHMENT 1

ANALYSIS REQUISITION



National Medical Services, Inc.

3701 Welsh Rd. • P.O. Box 438A
Willow Grove, Pennsylvania 19080-0437
(215) 867-4900 (800) 622-6871 FAX: (215) 657-2972

Biomonitoring for Environmental/Occupational Exposure • Criminalistics
Forensic Toxicology • Therapeutic Drug Monitoring

• CLIENT TO FILL IN SHADED AREAS ONLY •

PATIENT NAME (LAST, FIRST, MIDDLE) **DOE, JOHN**

PATIENT ID. NO. **38 3 14**

☐ FORENSIC ☒ STAT **6**

☐ Return Specimen **7**

SPECIMEN TYPE:

☒ Blood ☒ Urine ☐ Other **8**

☐ Plasma ☒ Hair ☐ Nail

☐ Serum ☐ Tissue

NOTE: REQUISITIONS WILL BE HANDLED AS NON-FORENSIC UNLESS OTHERWISE NOTED. REFER TO SERVICE DIRECTORY FOR FURTHER HANDLING INSTRUCTIONS.

SPECIMEN COLLECTION:

Date: **10/16/98**

Time: **345**

Random ☒ Timed ☐

Time: _____ HRS.

Volume: _____ ML

CONTROL NO. **000000**



ACCOUNT NO. **00000**



ACCOUNT NAME/ADDRESS

COMPANY NAME **ISSI**
ADDRESS **494 18th St**
ADDRESS **Suite 1450**
CITY STATE ZIP **Denver, CO 80202**

ACCOUNT INFORMATION:
(e.g. name of patient, medication)

10

0264	ALUMINUM	1856	DRUG SCREEN & ALCOHOL (BLOOD OR SERUM)	3360	PAROXITINE
0407	ARSENIO (SPECIATED)	1884	DRUG SCREEN (BLOOD OR SERUM)	3370	PCB'S (POLYCHLORINATED BIPHENYLE)
0480	ARSENIO (TOTAL)	8489	FENTANYL + METAB. (FORENSIC)	3380	PEMOLINE
0641	BENZENE (BLOOD)	2124	FLUVOXAMINE (LUVOX®)	3445	PESTICIDE/INSECTICIDE SCREEN*
0928	BENZODIAZEPINES W/GC/MS†	2134	FORMIC ACID	3784	POTASSIUM
0820	BENZTROPINE (COGENTIN®)	2143	GABAPENTIN	3978	PROPAFENONE
0803	BUPROPION (WELLBUTRIN®)	2921	HYDROCARBON • OXYGENATED VOLATILES	4105	RISPERIDONE + METABOLITE
0805	BUSPIRONE (BUSPAR®)	2390	IBUPROFEN	4180	SELENIUM
0921	CADMIUM BIOUPTAKE (BLOOD)	2418	INHALANTS - URINE METABS.	4185	SERTRALINE
8108	CADMIUM PANEL (OSHA)	2440	ISONIAZID*	4180	SILICON
0960	CANNABINOIDS (THC) W/ GC/MS	2484	LAMOTRIGINE (LAMICTAL®)	4205	SINEMET**†
0970	CARBAMAZEPINE + METABOLITE	2402	LEAD - SERUM	0841	SOTALOL
0971	CARBAMAZEPINE + METAB. - FREE	0020	LEAD IN BLOOD	4212	STRONTIUM
0972	CARBAMAZEPINE + METAB. - FREE/BOUND	2541	LSD SCREEN†	4280	SULFONYLUREA HYPOGLYCEMICS
1268	CHOLINESTERASE (RBC OR PLASMA)	2881	MAGNESIUM	4305	TACRINE (COGNEX®)
1261	CHROMIUM	2670	MANGANESE	4370	THALLIUM
1268	CLOMIPRAMINE AND METAB.	2870	MERCURY	4468	THIOXENE†
1278	CLONIDINE	6189	METALS PANEL - RBC's	4386	TICLOPIDINE (TICLID®)*
1287	CLOZAPINE + METABOLITE	2681	METALS/METALLOIDS† (BLOOD)	4331	TRAMADOL AND METABOLITE
1300	COCAINE + METAB. W/ GC/MS	3020	METHYLPHENIDATE (RITALIN®)*	4680	TRIFLUOPERAZINE (STELAZINE®)
1330	COPPER	3145	NEFAZADONE	4758	VENLAFAXINE + METABOLITE (EFFEXOR®)
3163	COTININE - URINE	0180	NICOTINE + COTININE METAB.	4800	WARFARIN
1840	DILTIAZEM	8880	OPIATES - FREE (ACTIVE) W/GC/MS	4844	ZINC

CONTROL NUMBER **000000**



NMS - WILLOW GROVE 19080-0437

CONTROL NUMBER **000000**



NMS - WILLOW GROVE 19080-0437

CONTROL NUMBER **000000**



NMS - WILLOW GROVE 19080-0437

CONTROL NUMBER **000000**



NMS - WILLOW GROVE 19080-0437

IF ANALYSIS DOES NOT APPEAR ABOVE,
PLEASE WRITE TEST NAME/NUMBER IN SPACE PROVIDED BELOW.

Hair = test code 0460

Blood = test code 6020

Urine = test code 0468

R Note _____ TONI _____

MLT

PL

RT QYT R/GYT BLT QT LT CPC GPC GYPC PPC OPC
BLV WJ VV CV RV DV LBLV HP WPO BLPO RPO
BRV QV LV

VERIFICATION:

NMS COPY

VER 1.7

Data Collection Log

[illegible]

TECHNICAL STANDARD OPERATING PROCEDURE
BLOOD LEAD SAMPLING

ATTACHMENT 2

Patient Names to be Used for Blind Quality Control Samples

Name	Social Security #
Kyle Anderson	527-55-3942
Harold Brame	304-77-9165
Rajeev Chaula	636-73-6452
Polly Davis	746-01-4495
Craig Ensley	430-67-2533
Alessandro Fortin	271-85-9411
Abel Glardon	401-77-1802
Floyd Harrison	629-54-4980
Robert Hendrickson	520-11-9257
Andrew Iverson	410-56-3309
Diana Isham	461-98-0835
Sarah Jennigan	529-57-0640
Raymond Jones	528-62-8117
Frank Knotts	825-24-1955
James Kutsko	539-30-9609
Lonnie Labriola	674-78-0370
Brian Lucero	665-07-7231
Kristine Molinari	455-14-8527
Anita Marshall	347-53-7037
Albert Musser	936-83-5385
Amy Noel	495-90-0510
Etsuko Nishimura	662-88-3825
Andrew Ochoa	652-97-6791
Carol Ottmer	520-92-0424
Beulah Peek	261-14-4322
Ardith Pritchard	566-59-2501
Roy Quinlan	510-50-6497
Agustin Quintero	427-74-0676
Ace Ratcliff	512-26-3959
Aaron Roybal	450-42-3918
Arturo Sigala	603-31-3864
Karl Steinbeck	548-30-5794
Anita Sanchez	599-10-4556
Kurt Swingle	416-61-3547
Lao Tizer	334-30-4184
Carrie Trupiano	605-63-4911
Murray Unell	655-91-6413
Chris Utz	524-52-0927
Benito Valdez	520-97-3678
Alvin Voight	527-21-9696
Barbara Waldinger	608-93-5468
Peter Wolfe	568-62-2315
Chong Yang	520-70-1753
Robert York	783-14-9328
Byron Johnson	680-79-8106
Heidi Ham	500-83-3425
Tim Curran	512-94-9847
Rebecca Utrup	352-07-7360

**Composite Hair Sampling for the Determination of Risk-Based Exposure to Total Arsenic
(SOP # VBI70-14)**

TECHNICAL STANDARD OPERATING PROCEDURE
HAIR SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

Date: November 30, 1999 (Rev. # 0)

SOP No. ISSI-VBI70- 14

Title: HAIR COLLECTION FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

APPROVALS:

Author _____ ISSI Consulting Group, Inc Date: November 30, 1999

SYNOPSIS: A standardized method for the collection of hair samples for subsequent determination of risk-based exposure to arsenic. Protocols for sample collection, and sample handling are provided.

Received by QA Unit:

REVIEWS:

TEAM MEMBER	SIGNATURE/TITLE	DATE
<u>EPA Region 8</u>	<u>[Signature]</u>	<u>2/14/00</u>
<u>ISSI Consulting Group, Inc.</u>	<u>W/S Butler</u>	<u>2/15/00</u>

Revision Date	Reason for Revision

TECHNICAL STANDARD OPERATING PROCEDURE

HAIR SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to provide a standardized method to be implemented by employees of EPA Region VIII or contractors and subcontractors supporting Region VIII projects and tasks. This SOP describes the equipment and operations used to sample hair. The procedure outlines the method for composite hair sampling that will ultimately be used for risk-based determination of arsenic concentrations. Site-specific deviations from the procedures presented in this document must be approved by the Project Manager or Regional Toxicologist prior to initiation of the sampling activity.

2.0 RESPONSIBILITIES

The contractor who is responsible for overseeing the biomonitoring activities (ISSI) will be responsible for checking all work performed and verifying that the work satisfies the specific tasks outlined by this SOP and the Project Plan. It is also the responsibility of the contractor to communicate the need for any deviations from this SOP with the appropriate USEPA Region 8 personnel (Remedial Project Manager, or Regional Toxicologist). It is the responsibility of the subcontractor collecting the sample (Concentra) to communicate with all personnel regarding specific collection objectives and to communicate with ISSI regarding any anticipated situations that require deviation from this SOP.

All personnel performing biological sampling are responsible for adhering to the applicable tasks outlined in this procedure while collecting samples.

3.0 EQUIPMENT

- alcohol wipes
- disposable latex gloves
- stainless steel scissors
- small plastic sampling vial (for short hair)
- large plastic sampling vial (for long hair)
- sealable plastic bags
- permanent marker or ink pen
- trash bag
- tape measure or ruler
- Analysis Requisition forms - will be provided by ISSI
- Consent forms - will be provided by ISSI
- Field Notebook - three-ring binder book used to store necessary forms that record and track samples collected as part of the VBI70 biomonitoring program. Binders will contain Data Collection Logsheets, and Analysis Requisition forms

TECHNICAL STANDARD OPERATING PROCEDURE
HAIR SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

4.0 COLLECTION OF HAIR SAMPLES

Hair is collected by cutting a small portion at the nape of the neck, using the procedure outlined below.

4.1 For hair samples less than two inches:

Wash hands thoroughly with soap and water prior to taking a hair sample. Put on a new pair of disposable gloves. Clean the scissors blades with a new alcohol wipe and allow to air dry. Tightly twist a ¼ inch diameter (approximately as thick as a pencil or about 0.5 g) bundle of hair from the nape of the neck. Carefully snip the hair as close to the scalp as possible. Use a tape measure or pocket ruler to measure the length of hair cut. Remove the cap from the small plastic sampling vial, and fill with loosely packed hair. Replace the cap and place the vial in the plastic bag. Affix a sample identification number to the outside of the vial, and to the Analysis Requisition form. Seal the bag and label the measured hair length with a permanent marker or ink pen. (Samples do not need to be refrigerated.) Use a new alcohol wipe to clean the scissor blades. After the scissors have been cleaned, dispose of the alcohol wipes and the disposable gloves.

Limited Sample: A minimum of 0.5g must be obtained for analysis. If the hair is too short and a 0.5g sample cannot be obtained in one bundle, several smaller bundles can be collected as described above, and placed into a single sample container.

4.2 For hair samples longer than two inches:

Wash hands thoroughly with soap and water prior to taking hair sample. Put on a new pair of disposable gloves. Clean the scissor blades with a new alcohol wipe. Tightly twist a ¼ inch diameter (approximately as thick as a pencil or about 0.5 g) bundle of hair from the nape of the neck. Carefully snip the hair as close to the scalp as possible. Use a tape measure or pocket ruler to measure the length of hair cut. Remove the cap from the large plastic sampling vial, and fill with loosely packed hair. Replace the cap and place the vial in the plastic bag. Affix a sample identification number to the outside of the vial, and to the Analysis Requisition form. Seal the bag and label the measured hair length with a permanent marker or ink pen. (Samples do not need to be refrigerated.) Use another new alcohol wipe to clean the scissor blades. After the scissors have been cleaned, dispose of the alcohol wipes and the disposable gloves in an appropriate container.

5.0 SAMPLE CONTAINERS AND LABELING

Following the procedures outlined in Section 4.0, samples will be collected directly into sample containers and labeled with a unique sample identification number. Each sample must have a sample identification number affixed to the collection container, and also attached to the Analysis Requisition form.

TECHNICAL STANDARD OPERATING PROCEDURE
HAIR SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

6.0 SITE CLEAN-UP

Dispose of all sampling equipment (used gloves, wipes) in a trash bag.

7.0 FIELD QUALITY ASSURANCE/QUALITY CONTROL

Adherence to quality assurance/quality control (QA/QC) procedures is an important part of field sample collection. Field QA/QC procedures include documentation requirements and preparation of field QC samples.

7.1 Field Quality Control Samples

The following quality control samples will be collected during this project to help assess the precision and accuracy of the data collected. All quality control samples will be inserted into the sample stream by ISSI.

Field Duplicate: Field duplicate samples are collected at the same time as the primary sample, and are submitted blind to the analytical laboratory to test both the precision of the analysis and the precision of sample collection. In this case, the field duplicate sample is a second sample of hair collected from the same individual. A minimum of 3 field duplicates will be collected from adult participants. If the number of samples exceeds 50, field duplicate samples will be collected at a frequency of 5% of all samples collected (1 field duplicate per 20 investigation samples collected). Field duplicate samples are submitted in a blind fashion to the analytical laboratory. In order to maintain anonymity, field duplicates will be labeled with 'dummy' patient names and inserted into the sample stream. A list of 'dummy' patient names is provided in Attachment 2. Direction for the selection and submission of field duplicates will be the responsibility of ISSI.

Blind Standard: The accuracy of an analytical method is evaluated by analyzing a sample medium fortified with a known concentration of target analytes that has been certified using the preparation and analysis method for that particular sample medium. Blind standards will be inserted into the sample stream using 'dummy' patient names to maintain the anonymity of the sample. A minimum of 3 blind standards at 2 arsenic concentrations will be inserted into the sample stream by ISSI.

7.2 Field documentation

A field notebook should be maintained by the personnel collecting hair samples. The field notebook is a three-ring binder that contains a Data Collection Log and the Analysis Requisition form for each patient. All entries in the field logbook must be signed and dated by the person recording the information.

TECHNICAL STANDARD OPERATING PROCEDURE

HAIR SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

The following information will be included on the Data Collection Log:

- date of collection
- time of collection
- name of sampling technician
- patient name
- patient's social security number
- descriptions of any deviations to this SOP and the reason for the deviation

An example of the Analysis Requisition form and the Data Collection Log is provided in Attachment 1.

8.0 DECONTAMINATION

Stainless steel scissors will be decontaminated using alcohol wipes, as described in Section 4.1 and 4.2. All other sampling equipment is not reusable and must be disposed in an appropriate container(s).

9.0 GLOSSARY

Project Plan - The written document that spells out the detailed site-specific procedures to be followed by the Project Leader and the clinic personnel.

10.0 REFERENCES

Paschal, D.C., E.S. DiPietro, D.L. Phillips and E.W. Gunter. 1989. Age Dependence of Metals in Hair in a Selected U.S. Population. Environmental Research. 48: 17-28.

USEPA. 1978. Human Scalp Hair: An Environmental Exposure Index for Trace Elements. II. Seventeen Trace Elements in Four New Jersey Communities (1972). EPA 600/1-78-37b

TECHNICAL STANDARD OPERATING PROCEDURE
HAIR SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

ATTACHMENT 1

Analysis Requisition form (example)
Biological Sample Logbook sheet

ANALYSIS REQUISITION



National Medical Services, Inc.
3701 Welsh Rd. • P.O. Box 430A
Willow Grove, Pennsylvania 19090-0437
(215) 867-4900 (800) 622-6671 FAX: (215) 657-2972

Biomonitoring for Environmental/Occupational Exposure • Criminalistics
Forensic Toxicology • Therapeutic Drug Monitoring

• CLIENT TO FILL IN SHADED AREAS ONLY •

PATIENT NAME (LAST) **DOE** (F) **JOHN**

PATIENT ID. NO. **38** (3) **14**

☐ FORENSIC ☒ STAT ☐ Return Specimen

SPECIMEN TYPE:
☒ Blood ☐ Plasma ☐ Serum
☒ Urine ☐ Hair ☐ Tissue

DATE: **12/16/98**
TIME: **345**
SPECIMEN COLLECTION: ☒ Timed ☐ Random

CONTROL NO. **000000**

ACCOUNT NO. **00000**

ACCOUNT NAME/ADDRESS
COMPANY NAME ISSI
ADDRESS 999 18th St
ADDRESS Suite 1450
CITY STATE ZIP Denver, CO 80202

ACCOUNT INFORMATION
(# of tubes or patient medications)

CONTROL NUMBER **000000**

NMS - WILLOW GROVE 19090-0437

CONTROL NUMBER **000000**

NMS - WILLOW GROVE 19090-0437

CONTROL NUMBER **000000**

NMS - WILLOW GROVE 19090-0437

CONTROL NUMBER **000000**

NMS - WILLOW GROVE 19090-0437

NMS - WILLOW GROVE 19090-0437

0264	ALUMINUM	1858	DRUG SCREEN (BLOOD OR URINE)	3350	PAROXITINE
0407	ARSENIC (SPECIATED)	1884	DRUG SCREEN (BLOOD OR URINE)	3370	PCBs (POLYCHLORINATED BIPHENYLS)
0480	ARSENIC (TOTAL)	8489	FENTANYL + METAB. (FORENSIC)	3380	PEMOLINE
0541	BENZENE (BLOOD)	2124	FLUVOXAMINE (LUVOX®)	3445	PESTICIDE/INSECTICIDE SCREEN*
0928	BENZODIAZEPINES W/GC/MS†	2134	FORMIC ACID	3784	POTASSIUM
0820	BENZTROPINE (COGENTIN®)	2143	GABAPENTIN	3978	PROPAFENDONE
0803	BUPROPION (WELLBUTRIN®)	2321	HYDROCARBON - OXYGENATED VOLATILES	4105	RISPERIDONE + METABOLITE
0805	BUSPIRONE (BUSPAR®)	2390	IBUPROFEN	4180	SELENIUM
0921	CADMIUM BIOUPTAKE (BLOOD)	2416	INHALANTS - URINE METABS.	4185	GERTRALINE
8108	CADMIUM PANEL (OSHA)	2440	ISONIAZID*	4190	SILICON
0860	CANNABINOIDS (THC) W/ GC/MS	2484	LAMOTRIGINE (LAMICTAL®)	4205	BINEMET**†
0870	CARBAMAZEPINE + METABOLITE	2402	LEAD - SERUM	0841	SOTALOL
0871	CARBAMAZEPINE + METAB. - FREE	8020	LEAD IN BLOOD	4212	STRONTIUM
0872	CARBAMAZEPINE + METAB. - FREE/BOUND	2541	LSD SCREEN†	4280	SULFONYLUREA HYPOGLYCEMICS
1255	CHOLINESTERASE (RBC OR PLASMA)	2581	MAGNESIUM†	4305	TACRINE (COGNEX®)
1261	CHROMIUM	2570	MANGANESE	4370	THALLIUM
1268	CLOMIPRAMINE AND METAB.	2570	MERCURY	4458	THIOXIMENE†
1275	CLONIDINE	6153	METALS PANEL - RBC's	4396	TICLOPIDINE (TICLID*)
1287	CLOZAPINE + METABOLITE	2561	METALS/METALLOIDS I (BLOOD)	4531	TRAMADOL AND METABOLITE
1300	COCAINE + METAB. W/ GC/MS	3020	METHYLPHENIDATE (RITALIN®)	4880	TRIFLUOPERAZINE (STELAZINE®)
1330	COPPER	3145	NEFAZADONE	4768	VENLAFAXINE + METABOLITE (EFFEXOR®)
3163	COTININE - URINE	8160	NICOTINE + COTININE METAB.	4800	WARFARIN
1840	DILTIAZEM	8860	OPIATES - FREE (ACTIVE) W/GC/MS	4844	ZINC

IF ANALYSIS DOES NOT APPEAR ABOVE,
PLEASE WRITE TEST NAME/NUMBER IN SPACE PROVIDED BELOW.

Hair = test code 0460

Blood = ⁽¹²⁾ test code 6020

Urine = test code 0468

R Note _____ TONI _____

MLT

PL

RT QYT R/QYT BLT QT LT CPC QPC GYPC PPC OPC
BLV WV YV CV RV QV LBLV NB WPO BLPO RPO
BRV QV LV

VERIFICATION:

NMS COPY

VER 1.7

Data Collection Log

[illegible]

TECHNICAL STANDARD OPERATING PROCEDURE
HAIR SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

ATTACHMENT 2

Patient names to be used for blind quality control samples

Patient Names to be Used for Blind Quality Control Samples

Name	Social Security #
Kyle Anderson	527-55-3942
Harold Brame	304-77-9165
Rajeev Chaula	636-73-6452
Polly Davis	746-01-4495
Craig Ensley	430-67-2533
Alessandro Fortin	271-85-9411
Abel Glardon	401-77-1802
Floyd Harrison	629-54-4980
Robert Hendrickson	520-11-9257
Andrew Iverson	410-56-3309
Diana Isham	461-98-0835
Sarah Jennigan	529-57-0640
Raymond Jones	528-62-8117
Frank Knotts	825-24-1955
James Kutsko	539-30-9609
Lonnie Labriola	674-78-0370
Brian Lucero	665-07-7231
Kristine Molinari	455-14-8527
Anita Marshall	347-53-7037
Albert Musser	936-83-5385
Amy Noel	495-90-0510
Etsuko Nishimura	662-88-3825
Andrew Ochoa	652-97-6791
Carol Ottmer	520-92-0424
Beulah Peek	261-14-4322
Ardith Pritchard	566-59-2501
Roy Quinlan	510-50-6497
Agustin Quintero	427-74-0676
Ace Ratcliff	512-26-3959
Aaron Roybal	450-42-3918
Arturo Sigala	603-31-3864
Karl Steinbeck	548-30-5794
Anita Sanchez	599-10-4556
Kurt Swingle	416-61-3547
Lao Tizer	334-30-4184
Carrie Trupiano	605-63-4911
Murray Unell	655-91-6413
Chris Utz	524-52-0927
Benito Valdez	520-97-3678
Alvin Voight	527-21-9696
Barbara Waldinger	608-93-5468
Peter Wolfe	568-62-2315
Chong Yang	520-70-1753
Robert York	783-14-9328
Byron Johnson	680-79-8106
Heidi Ham	500-83-3425
Tim Curran	512-94-9847
Rebecca Utrup	352-07-7360

Urine Sampling for the Determination of Risk-Based Exposure to Arsenic
(SOP # VBI70-15)

Date: November 30, 1999 (Rev. # 0)

SOP No. ISSI-VBI70- 15

Title: URINE COLLECTION FOR THE DETERMINATION OF RISK-BASED
EXPOSURE TO ARSENIC

APPROVALS:

Author _____ ISSI Consulting Group, Inc.

Date: November 30, 1999

SYNOPSIS: A standardized method for the collection of urine samples for subsequent determination of risk-based exposure to arsenic. Protocols for sample collection, and sample handling are provided.

Received by QA Unit:

REVIEWS:

TEAM MEMBER

SIGNATURE/TITLE

DATE

EPA Region 8

[Signature] / RPT

2/14/00

ISSI Consulting Group, Inc.

W.S. Batten

2/15/00

Revision Date	Reason for Revision

TECHNICAL STANDARD OPERATING PROCEDURE
URINE SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to provide a standardized method for collecting urine for subsequent determination of exposure to arsenic by residents. Urine samples from participating residents will be collected at a neighborhood clinic by study personnel, using the procedures described in this Standard Operating Procedure (SOP). All personnel involved with urine collection will be trained in this procedure prior to any sample collection. This SOP describes the equipment and operations used for collecting urine, using a procedure that will produce data that can be used to support risk evaluations. Site-specific deviations from the procedures outlined in this document must be approved by the USEPA Region 8 Remedial Project Manager, or Regional Toxicologist prior to initiation of the sampling activity.

2.0 RESPONSIBILITIES

The contractor who is responsible for overseeing the biomonitoring activities (ISSI) will be responsible for checking all work performed and verifying that the work satisfies the specific tasks outlined by this SOP and the Project Plan. It is also the responsibility of the contractor to communicate the need for any deviations from this SOP with the appropriate USEPA Region 8 personnel (Remedial Project Manager, or Regional Toxicologist). It is the responsibility of the subcontractor collecting the sample (Concentra) to communicate with all personnel regarding specific collection objectives and to communicate with ISSI regarding any anticipated situations that require deviation from this SOP.

All personnel performing biological sampling are responsible for adhering to the applicable tasks outlined in this procedure while collecting samples.

3.0 EQUIPMENT

- Collection containers - certified arsenic-free, large-mouth sterile collection cup with screw-top lid
- Gloves - Disposable, latex, powderless
- Plastic ziplock bags
- Chain-of-Custody forms - will be provided by ISSI
- Consent Form - will be provided by ISSI
- Field notebook - a three-ring binder book that will store necessary forms used to record and track samples collected as part of the VBI70 biomonitoring program. Binders will contain chain-of-custody forms and Data Collection Logsheets.

TECHNICAL STANDARD OPERATING PROCEDURE
URINE SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

4.0 COLLECTION OF URINE SAMPLES

Urine samples will be collected from participating residents. Each participant will be directed to the collection facility (Concentra Medical Center). Participating residents will arrive at the collection facility with a voucher provided by ISSI. Concentra personnel will fill out a chain-of-custody form (example provided in Attachment 1) for each sample. All participants will be instructed as to the approved procedure for collecting and submitting urine samples. Samples will be clearly marked with the patient's name, date of collection, and patient's social security number. Each sample must have a sample identification label affixed to the outside of the collection cup, and also affixed to the chain-of-custody form. All samples must be tracked using the field notebook, as described in Section 6.2

Prior to and following urination, each participant must wash their hands.

Urine samples will be collected by taking the wide mouthed bottle into the bathroom. Start to urinate into the toilet as you normally do. After urination has started, collect the sample by intercepting the urine stream in mid-air with the wide-mouth bottle. Fill the bottle at least half full with urine and stop collection by moving the bottle out of the urine stream.

Children should be accompanied by their parent or guardian into the bathroom and their sample should be collected by an adult. Adults and teenagers may use the same sample collection techniques as children, but do not require assistance in sample collection.

Following collection, the container lid must be tightly secured.

5.0 SAMPLE CONTAINERS AND LABELING

Following the procedures outlined in Section 4.0, samples will be collected directly into sample containers and labeled with a unique sample identification number. Each sample must have a sample identification number affixed to the collection cup, and also attached to the chain-of-custody form.

6.0 FIELD QUALITY ASSURANCE/QUALITY CONTROL

Adherence to quality assurance/quality control (QA/QC) procedures is an important part of field sample collection. Field QA/QC procedures include documentation requirements and preparation of field QC samples.

6.1 Field Quality Assurance Samples

The following quality control samples will be collected during this project to help assess the

TECHNICAL STANDARD OPERATING PROCEDURE
URINE SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

precision and accuracy of the data collected. All quality control samples will be inserted into the sample stream by ISSI.

Field Duplicate: Field duplicate samples are collected at the same time as the primary sample, and are submitted blind to the analytical laboratory to test both the precision of the analysis and the precision of sample collection. In this case, the field duplicate sample is a second sample of urine collected from the same individual. This sample will be collected by filling a second cup immediately following the first cup. A minimum of 3 field duplicates will be collected from participating adults. If the number of participants exceeds 50, field duplicate samples will be collected at a frequency of 5% of all samples collected (1 field duplicate per 20 investigation samples collected). Field duplicate samples are submitted in a blind fashion to the analytical laboratory. In order to maintain anonymity, field duplicates will be labeled with 'dummy' patient names and inserted into the sample stream. A list of 'dummy' patient names is provided in Attachment 2. Direction and submission of field duplicates will be the responsibility of ISSI.

Blind Standard: The accuracy of an analytical method is evaluated by analyzing a sample medium fortified with a known concentration of target analytes that has been certified using the preparation and analysis method for that particular sample medium. Blind standards will be inserted into the sample stream using 'dummy' patient names to maintain the anonymity of the sample. A minimum of 3 blind standards at 2 arsenic concentrations will be inserted into the sample stream by ISSI.

6.2 Field documentation

A field notebook should be maintained by the personnel collecting blood samples. The field notebook is a three-ring binder that contains a Data Collection Log and the Analysis Requisition form for each patient. All entries in the field logbook must be signed and dated by the person recording the information.

The following information will be included on the Data Collection Log:

- date of collection
- time of collection
- name of sampling technician
- patient name
- patient's social security number
- descriptions of any deviations to this SOP and the reason for the deviation

An example of the Analysis Requisition form and the Data Collection Log is provided in Attachment 1.

TECHNICAL STANDARD OPERATING PROCEDURE
URINE SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

7.0 DECONTAMINATION

Biological sampling equipment will not be re-used. All sampling equipment must be disposed in the appropriate container(s).

8.0 GLOSSARY

Project Plan - The written document that spells out the detailed site-specific procedures to be followed by the Project Leader and the Clinic Personnel.

9.0 REFERENCES

Agency for Toxic Substances and Disease Registry, 1998. Exposure Investigation, Milltown Reservoir Sediments National Priorities List Site, Clark Fork River Operable Unit, Deer Lodge, Powell County Montana, U.S. Department for Health and Human Services.

TECHNICAL STANDARD OPERATING PROCEDURE
URINE SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

ATTACHMENT 1

ANALYSIS REQUISITION



National Medical Services, Inc.

3701 Welsh Rd. • P.O. Box 438A
Willow Grove, Pennsylvania 19080-0437
(215) 867-4900 (800) 622-6871 FAX: (215) 657-2972

Biomonitoring for Environmental/Occupational Exposure • Criminalistics
Forensic Toxicology • Therapeutic Drug Monitoring

• CLIENT TO FILL IN SHADED AREAS ONLY •

PAYMENT NAME (LAST, FIRST, MIDDLE) **DOE, JOHN**

PAYMENT C.O. NO. **38 3 14**

☐ FORENSIC ☐ STAT ☐ STAT ☐ STAT

SPECIMEN TYPE:

☒ Blood ☐ Plasma ☐ Serum ☐ Urine ☐ Hair ☐ Tissue

SPECIFY

SPECIMEN COLLECTION

Date: **10/16/98**

Time: **3:45 PM**

☒ Random ☐ Timed

Time: _____ Hrs.

Volumetric _____ MLE

CONTROL NO. **000000**

ACCOUNT NO. **000000**

ACCOUNT NAME/ADDRESS

COMPANY NAME ISSI
ADDRESS 494 18th St
ADDRESS Suite 1450
CITY STATE ZIP Denver, CO 80202

ACCOUNT INFORMATION
(e.g., status of patient, medication)

10

0264	ALUMINUM	1858	DRUG SCREEN & ALCOHOL (BLOOD OR SERUM)	3360	PAROXITINE
0407	ARSENIC (SPECIATED)	1884	DRUG SCREEN (BLOOD OR SERUM)	3370	PCB (POLYCHLORINATED BIPHENYL)
0460	ARSENIC (TOTAL)	8489	FENTANYL + METAB. (FORENSIC)	3380	PENICILLIN
0641	BENZENE (BLOOD)	2124	FLUVOXAMINE (LUVOX®)	3445	PESTICIDE/INSECTICIDE SCREEN*
0928	BENZODIAZEPINES W/GC/MS†	2134	FORMIC ACID	3784	POTASSIUM
0820	BENZTROPINE (COGENTIN®)	2143	GABAPENTIN	3978	PROPANENONE
0803	BUPROPION (WELLBUTRIN®)	2321	HYDROCARBON + OXYGENATED VOLATILES	4103	RISPERIDONE + METABOLITE
0805	BUSPIRONE (BUSPAR®)	2390	IBUPROFEN	4180	SELENIUM
0921	CADMIUM BIOUPTAKE (BLOOD)	2418	INHALANTS - URINE METABS.	4183	SERTRALINE
8108	CADMIUM PANEL (OSHA)	2440	ISONIAZID*	4180	SILICON
0960	CANNABINOIDS (THC) W/ GC/MS	2484	LAMOTRIGINE (LAMICTAL®)	4205	SINEMET**†
0970	CARBAMAZEPINE + METABOLITE	2402	LEAD - SERUM	0841	SOTALOL
0871	CARBAMAZEPINE + METAB. - FREE	8020	LEAD IN BLOOD	4212	STRONTIUM
0972	CARBAMAZEPINE + METAB. - FREE/BLOOD	2541	LSD SCREEN†	4280	SULFONYLUREA HYPOGLYCEMICS
1266	CHOLINESTERASE (RBC OR PLASMA)	2881	MAGNESIUM	4305	TACRINE (COGNEX®)
1261	CHROMIUM	2570	MANGANESE	4370	THALLIUM
1268	CLOMIPRAMINE AND METAB.	2670	MERCURY	4460	THIOXENE†
1275	CLONIDINE	6153	METALS PANEL - RBC*	4395	TICLOPIDINE (TICLOID®)
1287	CLOZAPINE + METABOLITE	2681	METALS/METALLOIDS (BLOOD)	4531	TRAMADOL AND METABOLITE
1300	COCAINE + METAB. W/ GC/MS	3020	METHYLPHENIDATE (RITALIN®)	4680	TRIFLUOPERAZINE (STELAZINE®)
1330	COPPER	3145	NEFAZADONE	4760	VENLAFAXINE + METABOLITE (EFFEXOR®)
3153	COTININE - URINE	8150	NICOTINE + COTININE METAB.	4800	WARFARIN
1840	DILTIAZEM	8860	OPiates - FREE (ACTIVE) W/GC/MS	4844	ZINC

CONTROL NUMBER **000000**

NMS - WILLOW GROVE 18080-0437

CONTROL NUMBER **000000**

NMS - WILLOW GROVE 18080-0437

CONTROL NUMBER **000000**

NMS - WILLOW GROVE 18080-0437

CONTROL NUMBER **000000**

NMS - WILLOW GROVE 18080-0437

IF ANALYSIS DOES NOT APPEAR ABOVE,
PLEASE WRITE TEST NAME/NUMBER IN SPACE PROVIDED BELOW.

Hair = test code 0460

Blood = ¹² test code 6020

Urine = test code 0468

R Note **TOmt**

MLT

PL

RT	QYT	R/GYT	BLT	QT	LT	CPC	QPC	GYPC	PPC	QPC
BLV	WV	VV	CV	RV	DV	LDLV	HP	WPO	BLPO	RPO
BRV	QV	LV								

NMS COPY

VER 1.7

Data Collection Log

[illegible]

TECHNICAL STANDARD OPERATING PROCEDURE
URINE SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

ATTACHMENT 2

Patient Names to be Used for Blind Quality Control Samples

Name	Social Security #
Kyle Anderson	527-55-3942
Harold Brame	304-77-9165
Rajeev Chaula	636-73-6452
Polly Davis	746-01-4495
Craig Ensley	430-67-2533
Alessandro Fortin	271-85-9411
Abel Glardon	401-77-1802
Floyd Harrison	629-54-4980
Robert Hendrickson	520-11-9257
Andrew Iverson	410-56-3309
Diana Isham	461-98-0835
Sarah Jennigan	529-57-0640
Raymond Jones	528-62-8117
Frank Knotts	825-24-1955
James Kutsko	539-30-9609
Lonnie Labriola	674-78-0370
Brian Lucero	665-07-7231
Kristine Molinari	455-14-8527
Anita Marshall	347-53-7037
Albert Musser	936-83-5385
Amy Noel	495-90-0510
Etsuko Nishimura	662-88-3825
Andrew Ochoa	652-97-6791
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Agustin Quintero	427-74-0676
Ace Ratcliff	512-26-3959
Aaron Roybal	450-42-3918
Arturo Sigala	603-31-3864
Karl Steinbeck	548-30-5794
Anita Sanchez	599-10-4556
Kurt Swingle	416-61-3547
Lao Tizer	334-30-4184
Carrie Trupiano	605-63-4911
Murray Unell	655-91-6413
Chris Utz	524-52-0927
Benito Valdez	520-97-3678
Alvin Voight	527-21-9696
Barbara Waldinger	608-93-5468
Peter Wolfe	568-62-2315
Chong Yang	520-70-1753
Robert York	783-14-9328
Byron Johnson	680-79-8106
Heidi Ham	500-83-3425
Tim Curran	512-94-9847
Rebecca Utrup	352-07-7360

**Preparation and Analysis Methods for Lead in Blood, Total Arsenic in Hair, and Inorganic
Arsenic in Urine**



National Medical Services, Inc.

Toxicology Specialists Worldwide Since 1970

3701 Welsh Road
Willow Grove, PA 19090
Phone: (215) 657-4900
1-800-522-6671
Fax: (215) 657-2972

NAME OF TEST:

LEAD in Blood Analysis
by Graphite Furnace Atomic Absorption Spectrometry

NMS # 6020

ANALYTE CLASSIFICATION:

Heavy Metal
Atomic Number: 82
Atomic Weight: 207.2
Valence: 2, 4

METHOD PRINCIPLE:

Lead in blood is determined using graphite furnace atomic absorption spectrometry. The samples are diluted with chemical modifier and injected directly into the graphite furnace. Concentrations are calculated using a calibration curve constructed from a series of blood standards.

SPECIMEN REQUIREMENTS:

Specimen	Volume	Volume	Volume
Blood	1.0 mL	0.5 mL	0.2 mL

SPECIAL HANDLING:

None

REPORTING LIMIT:

1 mcg/dL Blood

PHARMACOTOXICOLOGIC DATA:

None available

LIMITATIONS OF METHOD:

1. Quantitative results cannot exceed the highest working standard for that run.
2. There is no known interference for this analysis by GFAAS.

REFERENCES:

1. Toxicology and Biological Monitoring of Metals in Humans. Carr, Ellis & Carr (eds.) pp. 126-135, Lewis Publishers, Chelsea, MT, 1986
2. Department of Health, August 20, 1988, Regulations (34 Pa. B. 3697)
3. Health & Environment Digest, Lead: Assessing its Health. 2: 1-5, 1988
4. Jacobson, B.E., Lockitch G., Qulgley, G., Improved Sample Preparation for Accurate Determination of Low Concentrations of Lead in Whole Blood by Graphite Furnace analysis. Clin. Chem. 37: 515-19, 1991.
5. Boone, J., Hearn, T., Lewis, S., Comparison of Inter Laboratory Results for Blood Lead with Results from A Definitive Method, Clin. Chem. 25: 389-93, 1979.
6. Wang, ST., Peter Fr., The Stability of Human Blood Lead in Storage, J. Anal. Tox. 8: 85-8, 1985.
7. Fernandez, F.J., Hilligoss, D., An Improved Graphite Furnace Method for the Determination of Lead in Blood Using Matrix Modification and L'vov Platform, At. Spectrosc. 3: 130-1, 1982.

National Medical Services TESTS



NATIONAL MEDICAL SERVICES NEW TEST ANNOUNCEMENT

TOTAL INORGANIC ARSENIC & METABOLITES (Speciated Arsenic) TEST CODE: 0467

Sources of Exposure

Arsenic is the twentieth most abundant element in the earth's crust and may be found in all living organisms. It may be present in soil, food, shellfish, tobacco, coal dust and well water. The daily diet in the United States contains below 0.04 mg of arsenic but may contain up to 0.2 mg per day if the diet contains seafood. Individuals may be exposed to a number of different forms of arsenic from the environment and/or from their occupation. These different forms of arsenic have varying toxicities.

Non-toxic forms of arsenic include arsenocholine and arsenobetaine which are present in seafood and are commonly referred to as seafood or organic arsenic. Together they can reach levels exceeding 1000 mcg/mL urine within 1-2 days following a single meal of fish or shellfish.

The forms of arsenic which are toxic are collectively termed inorganic arsenic and methylated metabolites. These toxic forms of arsenic include trivalent arsenic, pentavalent arsenic, dimethylarsinic acid and methylarsonic acid, and are commonly referred to as total inorganic arsenic, non-dietary arsenic or speciated arsenic. Inorganic arsenic can be found in hazardous waste sites, pesticides, herbicides, glassware, marine paints, ant pastes and veterinary antihelminths. Inorganic (or non-dietary) arsenic is also involved in alloy production, pigment production, microchip production, and the smelting of copper, lead and zinc. The greatest source of human exposure today is through the use of arsenical pesticides, which accounts for over 80% of industrial arsenic exposure. Arsenic can be absorbed into the body following inhalation, ingestion or dermal contact.

Health Effects

Assessing chronic exposure to the toxic forms of arsenic (inorganic or non-dietary arsenic) may be difficult since the symptoms tend to be nonspecific. These symptoms usually involve diarrhea, abdominal pain, hyperpigmentation of the skin and dermal lesions. There may be localized edema, sore throat, salivation, garlic odor of the breath, cardiovascular and/or neurological effects. There is also epidemiological evidence suggesting a significant increase in the incidence of skin and lung cancer. Symptoms of acute exposure to inorganic arsenic may include nausea, vomiting, chest pain, cerebral edema, delirium, coma and death.

Laboratory Test Indications - Biologic Monitoring:

The American Conference of Governmental Industrial Hygienists (ACGIH) recommends monitoring workers exposed to arsenic by collecting and analyzing the end of the work week urine for total inorganic arsenic (Test Code 0467).

Total arsenic analysis (Test Code 0466) measures both inorganic and organic arsenic. This test can be used to monitor workers if the workers avoid seafood for at least two days prior to specimen collection. However, it is often difficult to control seafood intake prior to specimen collection. If an elevated result is obtained using this test, it is recommended that the urine is analyzed for total inorganic arsenic to determine whether the exposure is related to dietary or non-dietary arsenic.

Total Arsenic analysis (Test Code 0460) is more appropriate in blood, serum, plasma or

other tissues in cases of suspected poisoning or overexposure.

In addition to the above mentioned tests, our Hair Exposure analysis for Arsenic is appropriate for determining past exposure to arsenic (i.e. more than 7 days). Sometimes it is important to determine the time frame of arsenic poisoning. Segmentation of the hair can be performed to determine the approximate time of exposure. Please call the laboratory for segmentation fees, or for total inorganic (non-dietary) arsenic analysis in specimens other than urine.

Test Name:	Total Inorganic Arsenic, Urine (Speciated)	Total Arsenic, Urine	Total Arsenic, Serum, Plasma, Blood	Total Arsenic, Hair
Test Code:	0467	0466	0460	0460
Specimen Requirements:	10 mL End of Work Week Urine	10 mL End of work Week Urine. Avoid seafood consumption for 48 hours prior to sample collection.	4 mL Serum, Plasma or Blood. (All venipunctures should be performed using a royal blue top tube.)	500 mg Pencil Thick Hair. Bundle, cut at roots, and indicate root end if segmentation analysis is required.
Method of Analysis:	Flow Injection Atomic Spectroscopy	Graphite Furnace Atomic Absorption Spectroscopy	Graphite Furnace Atomic Absorption Spectroscopy	Graphite Furnace Atomic Absorption Spectroscopy
Reporting Limit:	10 mcg/L	20 mcg/L	5 mcg/L	Depends on weight of hair submitted.
Reference Range:	Reference Range (unexposed population): less than 20 mcg/L. Biological Exposure Index (BEI): 50 mcg/g creatinine.	Reference Range (unexposed population): less than 20 mcg/L. Seafood consumption within 2 to 3 days before specimen collection can markedly increase total arsenic levels. Biological Exposure Index (BEI): 50 mcg/g creatinine.	Physiologic (unexposed normal): less than 5 mcg/L. Seafood consumption within 2 to 3 days before specimen collection can markedly increase total arsenic levels.	Reporting limit determined each analysis. Usually 0.03 to 3 mcg/g hair.
References:	1. ACGIH American Conference of Governmental			

	<p>Industrial Hygienists. Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices. Cincinnati, 1991 - 1992.</p> <ol style="list-style-type: none">2. Vahter, M., Clin. Chem., 40, 678-80, 1994.3. Baselt, R.C., Cravey, R.H., Disposition of Toxic Drugs and Chemicals in Man, 3rd Edition, 65 - 69, 1989.
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6/97

For more information concerning Arsenic or other analyses, please call 800-522-6671.

-
- ▶ **NMS HOME PAGE**
 - ▶ **Featured Tests**
 - ▶ **Alphabetical Test Listing**
-

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National Medical Services, Inc.

Toxicology Specialists Worldwide Since 1970

3701 Welsh Road
Willow Grove, PA 19090
Phone: (215) 657-4900
1-800-522-6671
Fax: (215) 657-2972

NAME OF TEST:

**ARSENIC In Dialysis Water, Digested Sample, Liquid
by Graphite Furnace
Atomic Absorption Spectrometry**

NMS # 0480

ANALYTE CLASSIFICATION:

Metalloid
Atomic Number: 33
Atomic Weight: 74.92
Valence: 3,5

METHOD PRINCIPLE:

Graphite furnace atomic absorption spectrometry (GFAAS) is an atomic absorption technique which uses the characteristic wavelength absorbed from ground-state atoms of an analyte to determine trace metal concentrations. Zeeman background correction is employed in this method. Samples are injected directly into the graphite furnace with nickel nitrate chemical modifier. The Concentrations are calculated by the computer system using a calibration curve based on aqueous standards.

SPECIMEN REQUIREMENTS:

Specimen	Graphite Volume	Aspirator Volume	Aspirator Volume
Liquid	1.0 mL	0.5 mL	0.25 mL
Dialysis Water	2.0 mL	0.5 mL	0.25 mL
Tissue	0.5 g	0.1 g	0.03 g
Hair	0.5 g	0.1 g	0.03 g
Nail	0.5 g	0.1 g	0.03 g

For Tissue & Other Specimen Water Calibration

REPORTING LIMIT:

5 mcg/L for Dialysis Water, Liquid
Determined for each analysis for Digested Samples

PHARMACOTOXICOLOGIC DATA:

Current data is available in the laboratory computer system and on each individual patient report.

LIMITATIONS OF METHOD:

1. Quantitative results cannot exceed the highest working standard for that run.
2. There is no known interference for As analysis by GFAAS.

REFERENCES:

1. Paschal DC, Kimberly, MM, and Bailey, GG. Determination of Urinary Arsenic by Electrothermal Atomic Absorption with the L'vov Platform and Matrix Modification. Anal. Chimica Acta, pp. 179-186, (1980). (See NMS Tech File Database - Doc. #2926)
2. Schlemmer, G and Welz B. Palladium and Magnesium Nitrates, a More Universal Modifier for Graphite Furnace Atomic Absorption Spectrometry, Spectrochimica Acta, 41B, 1157-65 (1986).
3. Dix, K, et al. Arsenic Speciation by Capillary Gas-Liquid Chromatography, J. Chrom. Sci., 25, 164-169 (1987).

4. Foa, V. et al, The Speciation of the Chemical Forms of Arsenic In the Biological Monitoring of Exposure to Inorganic Arsenic, *The Sci. of the Total Envir.*, 34, 241-259 (1984).
5. Yamauchi, H., et al, Biological Monitoring of Arsenic Exposure to Gallium Arsenide - and Inorganic Arsenic - Exposed workers by Determination of Inorganic Arsenic and Its metabolites in Urine and Hair, *Am. Ind. Hyg. Assoc. J.*, 50, 606-12 (1989).
6. Versieck, J. and Cornelis, R., *Trace Elements in Human Plasma of Serum*, CRC Press (Boca Raton, Florida), p. 75 (1989).
7. Lauwery, R.R., *Industrial Chemical Exposure: Guidelines for Biological Monitoring*, Biomedical Publications (Davis, CA), p. 47 (1983).
8. Accumulated NMS data, 1990.

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3701 Welsh Road
Willow Grove, PA 19090
Phone: (215) 657-4900
1-800-522-6671
Fax: (215) 657-2972

NAME OF TEST:

**TOTAL INORGANIC (NON-DIETARY) ARSENIC IN URINE
by Hydride Generation**

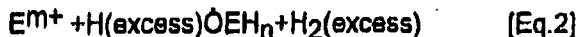
0468
NMS # 0467

ANALYTE CLASSIFICATION:

Metalloid
Atomic Number: 33
Atomic Weight: 74.92
Valence: 3,5

METHOD PRINCIPLE:

The hydride technique involves the reaction of acidified aqueous samples with a reducing agent, such as sodium borohydride. The sodium borohydride/acid reduction generates hydrides as shown in the follow equations (1).



where E = the analyte of interest and *m* may or may not equal *n*.

This reaction generates a volatile hydride which is transported to a quartz cell by means of an argon carrier gas. In the quartz cell, the hydrides are converted to gaseous metal atoms.

It is believed that atomization of the hydride occurs from collisions with free hydrogen radicals (2,3). In the quartz cell, the generated analyte atoms are contained in the path of a source lamp and a signal is generated by measuring the amount of light absorbed.

These signals can then be used to determine trace metal concentrations. Aqueous spiked standards and urine samples are first mixed with pre-reducing solution, and then sampled to a hydride generator through a flow injection analyzer. The concentrations are calculated by using the calibration curve based on aqueous spiked standards.

SPECIMEN REQUIREMENTS:

Specimen	Volume	Volume	Volume
Urine	5.0 mL	2.0 mL	0.25 mL
Dialysis Water	5.0 mL	2.0 mL	0.25 mL

REPORTING LIMIT:

10 mcg/L

- LIMITATIONS OF METHOD:**
1. Quantitative results cannot exceed the highest working standard or be less than the lowest working standard for that run.
 2. There are no known interferences for Inorganic Arsenic analysis by hydride generation.

PHARMACOTOXICOLOGIC DATA:

Current data is available in the laboratory computer system and on each individual patient report.

REFERENCES:

1. Dix, K., et al. Arsenic Speciation by Capillary Gas-Liquid Chromatography Chrom Sci., 25, 164-169 (1987).
2. Foa, V., et al. The Speciation of the Chemical Forms of Arsenic in the Biological Monitoring of Exposure to Inorganic Arsenic. The Sci. of the Total Envir., 34: 241-259 (1984).
3. Yamauchi, H., et al. Biological Monitoring of Arsenic Exposure to Gallium Arsenide - and Inorganic Arsenic - Exposed workers by Determination of Inorganic Arsenic and its metabolites in Urine and Hair, Am. Ind. Hyg. Assoc. J., 50:606-12 (1989).
4. Versleck, J. and Cornelis, R., Trace Elements in Human Plasma or Serum, CRC Press (Boca Raton, Florida), p. 75 (1989).
5. Lauwery, R.R., Industrial Chemical Exposure: Guidelines for Biological Monitoring, Biomedical Publications (Davis, CA), p. 47 (1983).
6. Accumulated NMS data, 1990.

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Attachment 2

- Letter to Residents
- Clinic Voucher
- Instructions for providing samples
- Informed consent forms
- Fact Sheet



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 8
999 18TH STREET - SUITE 500
DENVER, CO 80202-2466
<http://www.epa.gov/region08>

Ref: 8EPR-SR

Dear Resident:

As you know, the Environmental Protection Agency (EPA) collected soil samples from your yard as part of a study in your neighborhood to identify homes that may have elevated levels of arsenic or lead in soil. The results of the sampling of your yard indicate that a clean up is needed. With your cooperation, EPA will do the necessary cleanup at no cost to you.

In this period of time before EPA begins the cleanup of your yard, we wish to be sure that you and your family members are not being exposed to unsafe levels of arsenic or lead from the soil. The best way to do this is to measure the levels of arsenic in your urine and/or hair, and the level of lead in your blood. I encourage you and all the members of your family to volunteer to have these measurements taken. If any of the samples indicate higher than normal levels, I or another EPA representative will immediately meet with you to identify ways to reduce the exposures to safe levels. EPA may publish summaries of the measurements but your name and individual results will be kept strictly confidential.

If you choose to have the measurements taken, you will need to go to the Concentra Medical Center on 58th Street so that the required samples can be collected by a trained health technician. A map showing the location of the clinic is attached. EPA is offering this as a service to you and your family members and there is no cost to you. For each member of your family, all you need to do is fill out the attached form with their name and address and take the form and the enclosed voucher to the clinic. I will provide the results of the analyses to you as soon as they are reported to EPA.

If you have any questions about any part of this offer, don't hesitate to call me at (303) 312-6579, Ted Fellman at (303) 312-6119, or Patricia Courtney at (303) 312-6631.

Sincerely,

A handwritten signature in cursive script, reading "Bonnie Lavelle", is positioned above the printed name.

Bonnie Lavelle
Remedial Project Manager



Printed on Recycled Paper

**AUTHORIZATION FOR PARTICIPATION
CLINIC VOUCHER**

Project: ISSI Consulting Group, Inc. - VB-I70

Name: _____

Address: _____

Tests

1. Urine Arsenic
2. Hair Arsenic
3. Blood Lead

Authorized By: *Bonita Smith, EPA*

Date: 2/15/00

Note: This voucher is valid through Saturday, March 31, 2000.

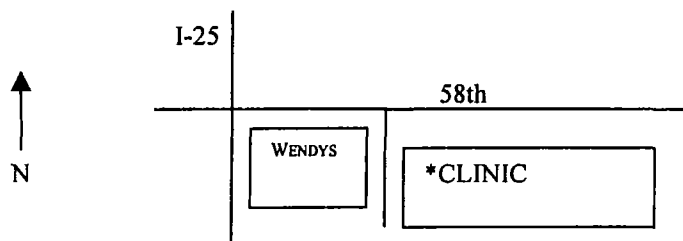
Clinic Location

CONCENTRA MEDICAL CENTERS

CONCENTRA NORTH
420 E. 58th Ave., Suite 111
Denver, CO 80216
(303) 292-2273

Hours: 7 a.m. - 6 p.m.
(Walk-in, No appointment required)

Directions: Take I-25 to 58th St. Go east on 58th. The clinic is directly east of Wendy's.



How samples are collected:

Blood: About 2 tablespoons of blood will be drawn from each person who volunteers to participate in this study.

Urine: You will be given a collection cup, and asked to provide about 3 ounces of urine. You should avoid seafood and red wine for three days before you go.

Hair: A small bundle of hair (about the width of a pencil) will be collected from an inconspicuous place (back of the neck or behind the ears).

CONSENT TO PARTICIPATE IN BIOMONITORING

Before agreeing that I will participate in this study, it is important that I read and understand the following explanation. It describes, in words that can be understood by a lay person, the purpose, procedures, benefits, risks and discomforts of the study and the precautions that will be taken. It also describes the alternatives available and the right to withdraw from the study at any time. It is important to understand that no guarantee or assurance can be made as to the results of the study. It is also understood that participation in this study is strictly voluntary and that refusal to participate in whole or any portion of the study will not result in penalty to me or my family, or influence the availability of standard medical treatment.

I, _____ have volunteered to participate in the biomonitoring program in my neighborhood.

I understand that by volunteering, I will receive information about the level of lead in my blood and/or the level of arsenic in my hair and/or urine.

OR

I, _____ wish to volunteer the following members of my family for blood lead, urinary arsenic and/or hair arsenic testing:

_____, age _____

_____, age _____

_____, age _____

_____, age _____

I understand that by volunteering, I will receive information about the level of lead in blood and/or arsenic in hair and/or urine in each member of my family who was tested.

Procedures

I understand that my voluntary participation in this biomonitoring program will involve some temporary inconvenience. I understand that I will be asked to go to a neighborhood location so that some blood, urine and/or hair can be collected from myself or members of my family.

I understand that I will not receive any compensation for my participation.

I _____, voluntarily agree to have the following samples collected as part of the biomonitoring program and consent to participation.

My participation involves (indicate which samples you would like to have collected):

- | Yes | No | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | urine (arsenic test). Allowing collection of about 3-4 oz. of urine. |
| <input type="checkbox"/> | <input type="checkbox"/> | hair (arsenic test). Allowing collection of a small amount of hair (approximately as wide as a pencil) from an area on the head in a minimally conspicuous area. |
| <input type="checkbox"/> | <input type="checkbox"/> | blood (lead test). Allowing collection of about 1-2 teaspoons of blood. |

Potential Benefits

I understand that this study may benefit me because it may help me to determine if myself or members of my family are being exposed to excess levels of lead or arsenic, and may help me find ways to reduce these exposures.

Risks, Discomforts and Precautions

I understand that collection of blood requires that a small needle be used to enter a vein. I also understand that a bruise can develop at the site where blood is drawn.

I understand that collection of urine will require me to urinate into a collection container at the laboratory.

I understand that collection of hair requires that a small amount of hair be collected from near my scalp. The amount of hair will be approximately the width of a pencil. The location for the collection will be selected in a minimally conspicuous area.

Confidentiality of Records

I understand that personal information will be kept in confidence by the biomonitoring staff. I also understand that neither I, nor any member of my family, will be identified by name in any reports of the results of the program.

I understand that I can obtain additional information about this program and my rights by contacting Bonnie Lavelle, at (303)-312-6579, or the following address:

U.S. Environmental Protection Agency
999 18th Street, Suite 500
Denver, Colorado 80202

I understand that I have the right to withdraw from having my blood, urine, or hair tested at any time and that withdrawing will not result in any penalty to me.

Based on the information provided above and having had the opportunity to discuss any concerns with the investigator or his designee, I voluntarily consent to participate in this biomonitoring program.

Printed Name of Volunteer
(Or name of Parent or Guardian if form is
Being signed for a minor)

Signature of Volunteer

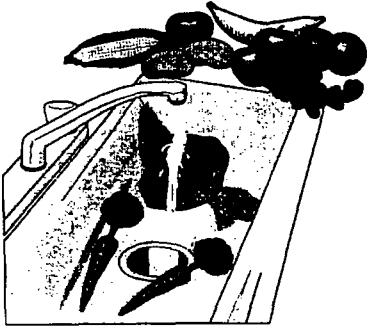
Name of Witness (Printed)

Signature of Witness

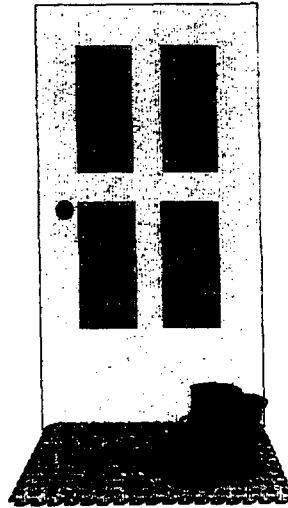
Date _____

Ways to protect your health

By keeping dirt from getting into your house and into your body



Wash and peel all fruits,
vegetables, and root crops



Wipe shoes on doormat
or remove shoes



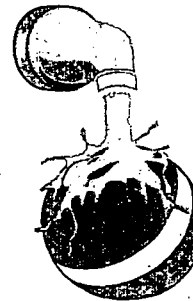
Don't eat food, chew gum,
or smoke when working
in the yard



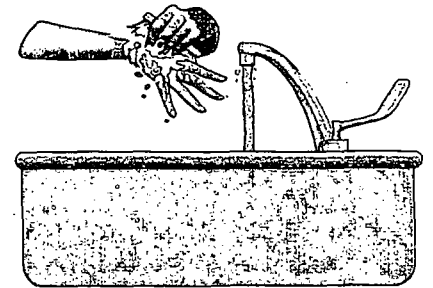
Damp mop floors and
damp dust counters and
furniture regularly



Wash dogs regularly



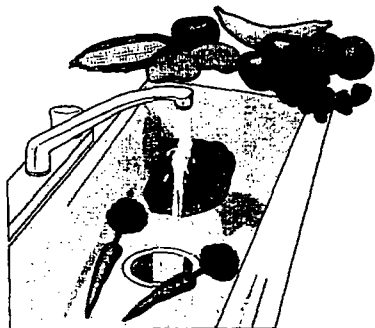
Wash children's toys
regularly



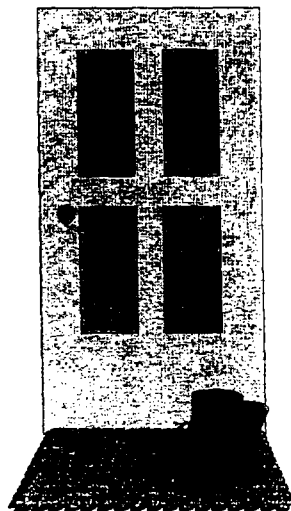
Wash children's hands
and feet after they have
been playing outside

Cómo proteger su salud

Evitando que el polvo entre a su casa o a su cuerpo



**Limpie y pele las frutas,
los vegetales y las viandas**



**Limpiese los zapatos en la alfombra
de la entrada o quítese los zapatos**



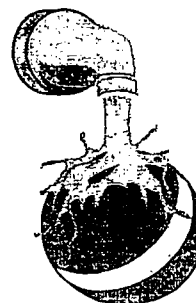
**No coma, mastique goma
de mascar, o fume mientras
esté trabajando en el patio**



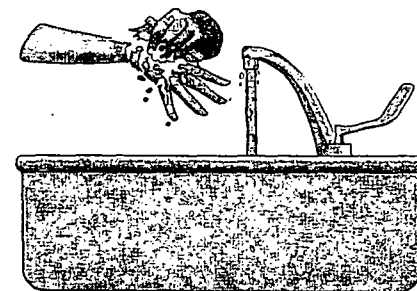
**Limpie la casa con
baño y trapeador húmedo**



**Baño a los perros
regularmente**



**Limpie regularmente
los juguetes de los niños**



**Lave las manos y los pies
de sus niños después de que
hayan estado jugando afuera**